colon and/or terminal ileum[, wherein the drug is not an immunosuppressive agent which is in solution].

13. (Twice amended) A method of delivering a vaccine to the lymphoid tissue present in the colon of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the vaccine and wherein the starch capsule is provided with a coating such that the vaccine is predominantly released from the capsule in the colon and/or terminal ileum[, wherein the drug is not an immunosuppressive agent which is in solution].

Remarks

Amendments to the claims

Claims 1 and 13 have been amended as discussed above. Support is found at least in the claims 1 and 13 of the PCT application WO 95/35100 and the United Kingdom priority document, GB 95/01458, and at p. 3, lines 25-29 of the PCT application.

Rejection under 35 U.S.C. § 112

Claims 1-13 were rejected (1) for allegedly lacking sufficient description under 35 U.S.C. § 112, first paragraph and (2) as allegedly indefinite under 35 U.S.C. § 112, second paragraph. The applicant respectfully disagrees if the rejection is applied to the claims as amended. Claims 1 and 13 have been amended to delete the phrase "wherein the drug is not an immunosuppressive agent which is in solution."

Double Patenting

Claims 1, 2, 5, 6, 8-13 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-8 of U.S. Patent No. 6,228,396 B1. Claims 3, 4, and 7 were rejected under the judicially created doctrine of

obviousness-type double patenting to the extent that they read on the rejected base claims. The applicant respectfully disagrees. However, to facilitate the prosecution of the claims, a terminal disclaimer will be submitted when the claims are otherwise allowed.

Rejections under 35 U.S.C. § 102

Claims 1-13 were rejected as allegedly anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 5,686,105 to Kelm et al. ("Kelm"). The applicant disagrees.

Kelm

Kelm discloses a pharmaceutical composition which can be delivered to the colon (col. 4, lines 54-60). The composition can be in the form of a starch capsule (col. 8, lines 63) coated with a polymeric material listed therein (col. 9 through col. 10). However, Kelm was filed on May 17, 1995, Ser. No. 442,920, which is continuation-in-part of Ser. No. 498,612, filed July 6, 1995, now U.S. Patent No. 5,631,022 ("the '022 patent"), which is a continuation of Ser. No. 139,364, filed on October 19, 1993, abandoned, and a continuation-in-part of Ser. No. 138,859, filed October 19, 1993, now U.S. Patent No. 5,514,663 ("the '663 patent").

The '022 patent discloses a pharmaceutical laxative composition formed of a picosulphate matrix and a proximal colonic delivery carrier (co. 1, line 66 to col. 2, line 6). The picosulphate matrix can be a powder which may include starch (col. 3, line 53). The proximal colonic delivery carrier can be in the form of compressed tablets, hard gelatin capsules, and soft elastic gelatin capsules (col. 4, lines 34-35). The '022 patent does not disclose the use of a starch capsule.

The '663 patent discloses a pharmaceutical composition formed of sennoside matrix and a proximal colonic delivery carrier (col. 2, lines 48-55; col. 3, lines 33 and 44). The sennoside matrix can be in the form of a powder which may include starch (col. 3, line 49). The proximal

colonic delivery carrier can have a pulse capsule (col. 6, line 5). The '663 patent also incorporate U.K. Patent Application Nos. 2,230,441A and 2,230,442A, whose equivalents correspond to WO 90/09168 ("WO 168") and WO 90/09169 ("WO 169"), respectively, and WO 91/12795 ("WO 795"), all by National Research Development Corporation (col. 6, lines 4-8). WO 168, WO 169 and WO 795 all describe capsules having a male part and a female part formed of two different materials having different water swellability, wetability, or solubility. None disclose the starch capsules defined in claims 1-13.

As such, the starch capsule disclosed in Kelm is only entitled to the filing date of May 17, 1995.

The claimed invention

Claims 1-13, as amended, are fully described and enabled in the priority document (see, for example, p. 3, lines 25-29, p. 4, lines 12-17 for claims 1, 12 and 13; p. 5, lines 9-18 for claims 2-3; p. 6, line 26 for claim 3; p. 6, line 27 and p. 7, line 1 for claim 4; p. 5, lines 10-14, p. 6, line 24 to p. 7, line 1, p. 7, lines 29-30 and p. 8, line 1 for claim 5; p. 6, lines 4-12 for claim 6; p. 5, lines 25-30 for claim 7; p. p. 5, lines 16-17 for claim 8; p. 8, lines 14-23 for claim 9; p. 8, lines 5-7 for claim 10; p. 8, lines 6-7 for claim 11; and examples 1-5 of the PCT application). Therefore, claims 1-13, as amended, are fully entitled to priority date of the priority document, U.K. Application No. 9412394.0, which is June 21, 1994. This date is about eleven months prior to the starch capsule disclosed in Kelm, which was first disclosed in the application filed on May 17, 1995.

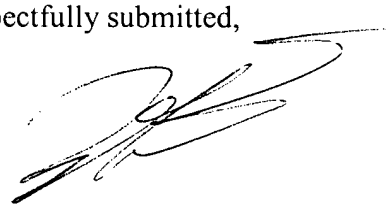
Therefore, to the extent Kelm is relevant, Kelm is not prior art citable against claims 1-13, as amended, under 35 U.S.C. § 102(e).

Rejection under 35 U.S.C. § 103

As the foregoing discussion demonstrates, the starch capsule disclosed in Kelm is only entitled to a priority date of May 17, 1995, Kelm can not be cited as a reference to hold claims 1-13 as obvious under 35 U.S.C. § 103.

Allowance of all claims 1-13 is earnestly solicited. A copy of the claims as pending upon entry of the amendments is attached in the Appendix for the Examiner's convenience.

Respectfully submitted,



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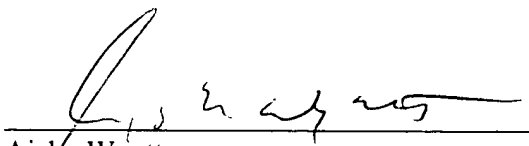

Aisha Wyatt

Date: October 11, 2001

APPENDIX I: Marked-up Copy of Claims as Pending

1. (Twice amended) A drug delivery composition for delivering a drug to the colonic region comprising a starch capsule containing the drug and wherein the starch capsule is provided with a coating such that the drug is predominantly released from the capsule in the colon and/or terminal ileum[, wherein the drug is not an immunosuppressive agent which is in solution].

2. A drug delivery composition according to claim 1 wherein the coating comprises a material which dissolves at a pH of 5 or above.

3. A drug delivery composition according to claim 1 wherein the coating comprises a material which is redox-sensitive.

4. A drug delivery composition according to claim 3 wherein the coating comprises an azopolymer or a disulphide polymer.

5. A drug delivery composition according to claim 1 wherein the coating comprises a material which is degraded by enzymes or bacteria present in the colon.

6. A drug delivery composition according to claim 2 wherein the coating comprises methylmethacrylate or a copolymer of methacrylic acid and methyl methacrylate.

7. A drug delivery composition according to claim 2 wherein the coating comprises a cellulose ester.

8. (Amended) A drug delivery composition according to claim 1 wherein the coating has a thickness in the range of 80 μm to 300 μm.

9. (Amended) A drug delivery according to claim 1 wherein the drug is one which acts locally in the colon.

10. (Amended) A drug delivery composition according to claim 1 wherein the drug is for systemic delivery and systemic action.

11. (Amended) A drug delivery composition according to claim 1 wherein the drug is a vaccine for delivery to the lymphoid tissue of the colon.

12. A method of delivering a drug to the colonic region of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the drug and wherein the starch capsule is provided with a coating such that the drug is predominantly released from the capsule in the colon and/or terminal ileum.

13. (Twice amended) A method of delivering a vaccine to the lymphoid tissue present in the colon of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the vaccine and wherein the starch capsule is provided with a coating such that the vaccine is predominantly released from the capsule in the colon and/or terminal ileum[, wherein the drug is not an immunosuppressive agent which is in solution].